

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 July 2002 (18.07.2002)

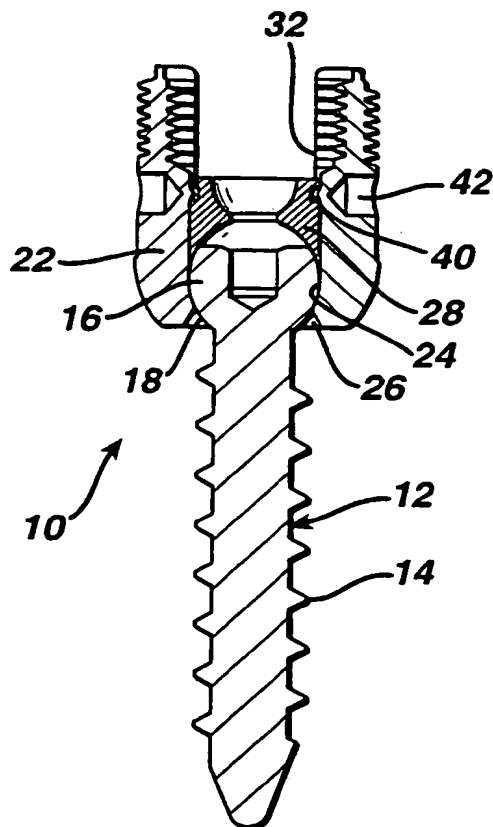
PCT

(10) International Publication Number
WO 02/054966 A2

- (51) International Patent Classification⁷: **A61B 17/70** (74) Agents: JOHNSON, Philip, S. et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003 (US).
- (21) International Application Number: PCT/US02/00814
- (22) International Filing Date: 11 January 2002 (11.01.2002) (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/261,129 12 January 2001 (12.01.2001) US
- (71) Applicant: DEPUY ACROMED, INC. [US/US]; 325 Paramount Drive, Raynham, MA 02767-0350 (US). (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
- (72) Inventor: GLASCOTT, Craig; 6612 Pineview Court, Boston Heights, OH 44236 (US).

[Continued on next page]

(54) Title: POLYAXIAL SCREW WITH IMPROVED LOCKING



(57) Abstract: A polyaxial pedicle screw assembly incorporates a concave portion on a receiver which mates with a convex surface on a head of the screw to form a ball joint. The radius of at least a portion of the concave surface is less than a radius of the mating convex portion whereby to create an interference fit.

WO 02/054966 A2



(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *without international search report and to be republished upon receipt of that report*

Polyaxial Screw with Improved Locking

5

Field of the Invention

10 The present invention relates to a polyaxial pedicle screw.

Background

15 Polyaxial pedicle screws such as disclosed in Biedermann et al.'s US Patent No. 5,443,467, incorporated herein by reference, are used for connecting vertebrae to rods in spinal surgery. They incorporate a ball joint at the connection to the rod to allow the surgeon some flexibility in placing the screws. Tightening a nut on the screw compresses the ball
20 joint components to lock the angular position of the ball joint.

Summary of the Invention

25 The present invention, improves the locking force achieved when locking the ball joint.

A pedicle screw assembly according to the present invention comprises a screw having a head with a convex
30 portion and a receiver receiving the head. The receiver also receives an elongate member, such as a spinal fixation rod. The receiver has a concave portion which has a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby to create an interference
35 fit between the convex portion of the head and the concave portion of the receiver.

Preferably, a nut on the receiver compresses the convex portion of the head into the concave portion of the receiver. In one convenient orientation, the receiver comprises a U-shaped portion for receiving the elongated member. Preferably, the concave portion of the receiver is formed of titanium. Although other shapes may be employed, in one preferred orientation each of the concave portion and convex portion have a spherical shape. Any shapes which allow rotational freedom of the head and receiver prior to engagement of the surfaces would suffice.

In one preferred embodiment the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof and the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture. The receiver further comprises a channel therethrough opposite the aperture, the channel receiving the elongate member.

The pedicle screw can further comprises a compression member between the elongate member and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an interference fit between the head and the pressure member.

The difference in the radius of curvature between the convex and concave portions in one embodiment is about 0.05 mm.

Brief Description of the Drawings

FIG. 1 is a cutaway view of a pedicle screw according to the present invention;

FIG. 2 is an additional cutaway view of the screw of FIG. 1 with rod and locking nuts removed for clarity; and

FIG. 3 is a detailed cutaway view of a portion of the receiver of FIG. 1.

Detailed Description

FIGS. 1 and 2 illustrates a polyaxial screw assembly according to the present invention. It comprises a screw 12 having cancellous threads 14 for insertion into the cancellous bone of a vertebra, especially through the pedicle. A spherically shaped head 16 has a convex surface 18 and a tool recess 20 for receiving a hex driver or other tool (not shown). The head 16 is received within a tubular receiver 22 having an internal concave surface 24 and an adjacent opening 26. The convex surface 18 of the head 16 mates with the concave surface 24. The opening 26 is smaller than the head 16 so that the screw 12 can project out of the opening 26 without falling out of the receiver 22.

A pressure disk 28 sits atop the head 26 and has a surface 30 of mating shape to that of the head 26. The receiver also has a U-shaped portion 32 which receives an elongated rod 34. The rod 34 is used to connect adjoining vertebrae as is known in the art. An internal nut 36 and external nut 38 compress the rod 34 against the pressure disk 28 which in turn compresses the head convex portion 18 into the receiver concave portion 24 and locks the angular position of the receiver 22 with respect to the screw 12.

The pressure disk 28 preferably has a lateral indentation 40 into which a material on the receiver 22 is swaged 42 to hold the pressure disk 28 within the receiver 22 but allow
5 some movement therein.

FIG. 3 illustrates the feature which improves the locking of the receiver 22 with respect to the screw 12 over prior similar screw assemblies. The concave surface 26 has a
10 slightly smaller radius of curvature than does the convex surface 18 so that when the two are compressed together, the material deforms somewhat to allow the surfaces to mate in an interference fit and thus enhances the grip between the
15 surfaces.

Tests of the deflection of the screw 12 under a torque load versus a prior screw show a significant decrease in deflection versus the prior screw, thus less slippage and better locking. Tables 1 and show the results of tests of
20 screws with and without the interference fit. The seven screws in Table 1 were formed of stainless steel and the seven screws in Table 2 of titanium. The screws labeled Magnum contain the interference fit and the others did not. The screws are of similar dimensions; the numbers listed after the
25 screw refer to the rod size. The tests consist of locking the screws to a uniform torque and then applying a lateral force to the screw 12 to induce a torque at the head 16. The load at an offset of 0.5mm and the stiffness were assessed for each sample. The screws with the interference fit of the present
30 invention exhibited gains in both parameters.

Table 1

Static Cantilever Beam Evaluation
 Moss-Miami (no interference fit) vs.
 Moss-Miami Magnum (interference fit)
 Stainless Steel

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2107	0.2188	0.2121	0.2926	0.2483	0.2349	0.3571	0.25	0.05
Moss-Miami Magnum 6.34	0.2470	0.3101	0.3678	0.2752	0.2926	0.3074	0.2618	0.29	0.04
	Stiffness N/mm								
Moss-Miami 6.0	602.2	459.8	229.9	594.3	245.8	538.8	570.8	463.1	160.99
Moss-Miami Magnum 6.34	637.0	705.2	627.8	611.4	753.2	721.1	689.8	677.9	53.27

Table 2

Static Cantilever Beam Evaluation
 Moss-Miami (no interference fit) vs.
 Moss-Miami Magnum (interference fit)
 Titanium

Specimen	1	2	3	4	5	6	7	Avg	Std Dev
	Load at Offset 0.5mm (Kn)								
Moss-Miami 6.0	0.2859	0.3047	0.2389	0.3074	0.2959	0.2403	0.3302	0.28	0.04
Moss-Miami Magnum 6.34	0.3730	0.4495	0.4502	0.4929	0.5348	0.5342	0.5114	0.48	0.06
	Stiffness N/mm								
Moss-Miami 6.0	451.9	404.9	293.3	467.7	404.1	316.9	396.4	390.7	64.58
Moss-Miami Magnum 6.34	707.4	572.1	573.9	526.6	580.0	578.7	517.1	584.5	58.38

In one preferred embodiment, the head convex surface 18
 would have a diameter of 6.995 mm and the mating receiver

concave surface 24 would have a diameter of 6.88 mm. Similar interference dimensions could also be applied to the mating interface of the pressure disk surface 30 and the head 16.

- 5 While the invention has been described with regard to a particular embodiment thereof, those skilled in the art will understand, of course, that the invention is not limited thereto since modifications can be made by those skilled in the art, particularly in light of the foregoing teachings.
- 10 Reasonable variation and modification are possible within the foregoing disclosure of the invention without the departing from the spirit of the invention.

IN THE CLAIMS

1. A pedicle screw assembly comprising:

a screw having a head with a convex portion;

5 a receiver receiving the head and an elongated member; and

the receiver having a concave portion, the concave portion having a radius of curvature which is less than a radius of curvature of the convex portion of the head whereby
10 to create an interference fit between the convex portion of the head and the concave portion of the receiver.

2. A pedicle screw assembly according to claim 1 and further comprising a nut on the receiver which compresses the
15 convex portion of the head into the concave portion of the receiver.

3. A pedicle screw assembly according to claim 2 wherein the receiver comprises a U-shaped portion for
20 receiving the elongated member.

4. A pedicle screw assembly according to claim 2 wherein the concave portion of the receiver is formed of titanium.
25

5. A pedicle screw assembly according to claim 1 wherein each of the concave portion and convex portion have a spherical shape.

30 6. A pedicle screw assembly according to claim 1 wherein the screw comprises an elongated shank having bone threads thereon and the head located at one end thereof;

wherein the receiver comprises a body having an aperture therethrough for receiving the shank and having the concave portion located at the aperture;

wherein the receiver further comprises a channel
5 therethrough opposite the aperture, the channel receiving the elongate member.

7. A pedicle screw according to claim 6 and further comprising a compression member between the elongate member
10 and the head; the head having a second convex portion facing the compression member and the compression member having a second concave portion facing the head, the second concave portion having a radius of curvature less than a radius of curvature of the second convex portion whereby to create an
15 interference fit between the head and the pressure member.

8. A pedicle screw according to claim 1 wherein the radius of curvature of the concave portion is about 0.05 mm smaller than the radius of curvature of the convex portion.

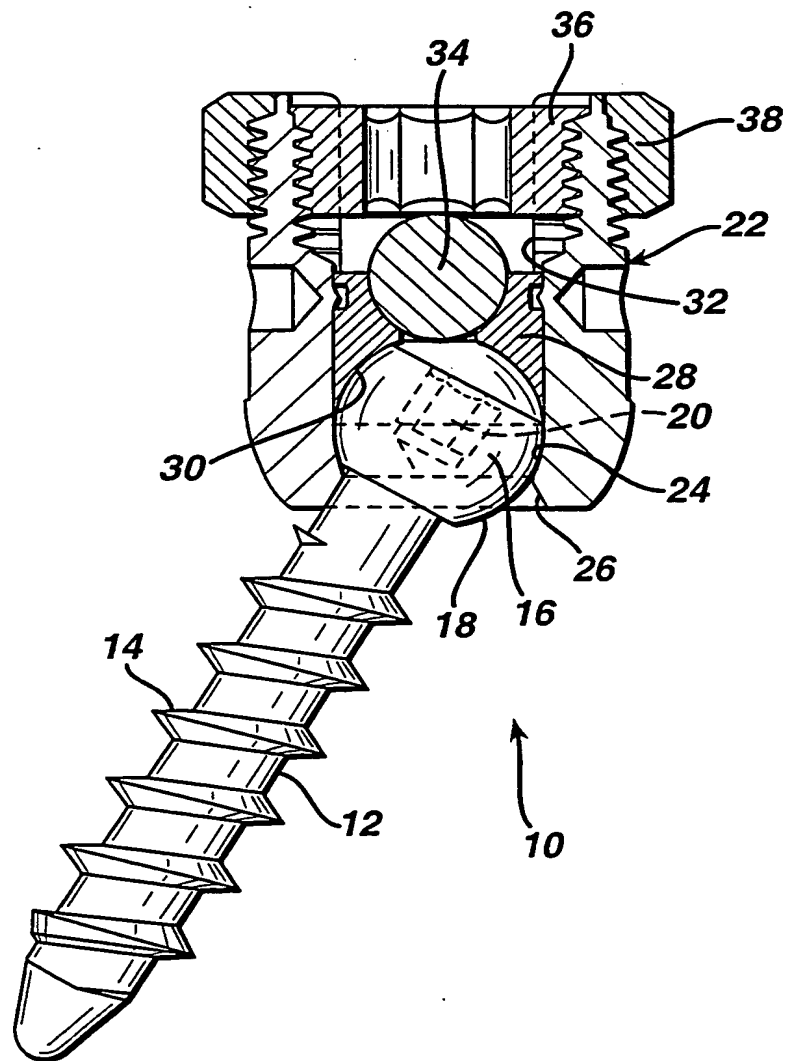
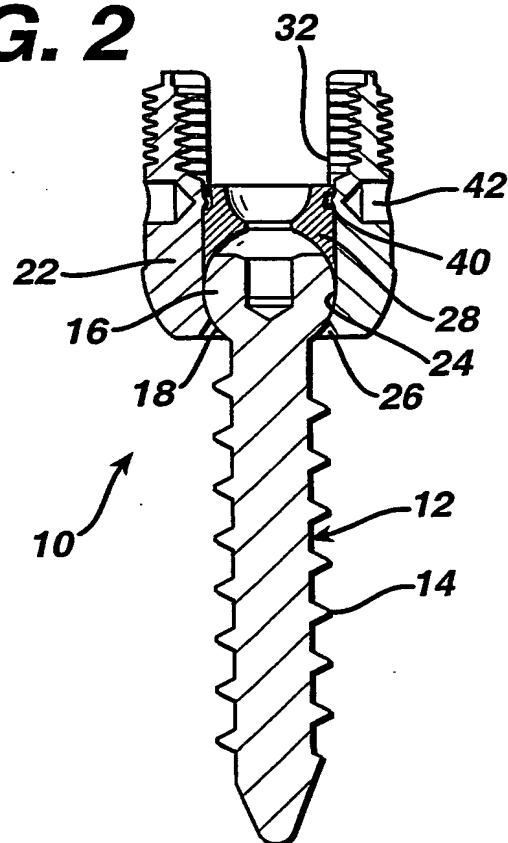
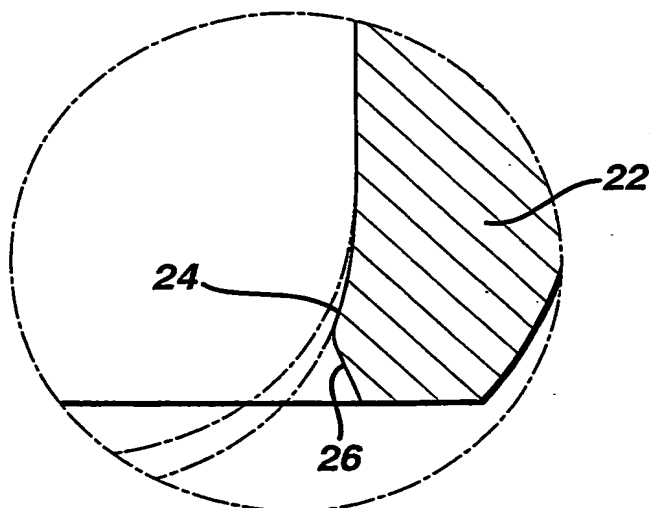
FIG. 1

FIG. 2**FIG. 3**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 July 2002 (18.07.2002)

PCT

(10) International Publication Number
WO 02/054966 A3

(51) International Patent Classification⁷: **A61B 17/70**

(74) Agents: **JOHNSON, Philip, S. et al.**; Johnson & Johnson,
One Johnson & Johnson Plaza, New Brunswick, NJ 08933-
7003 (US).

(21) International Application Number: **PCT/US02/00814**

(22) International Filing Date: **11 January 2002 (11.01.2002)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
60/261,129 **12 January 2001 (12.01.2001)** **US**

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(71) Applicant: **DEPUY ACROMED, INC.** [US/US]; 325
Paramount Drive, Raynhan, MA 02767-0350 (US).

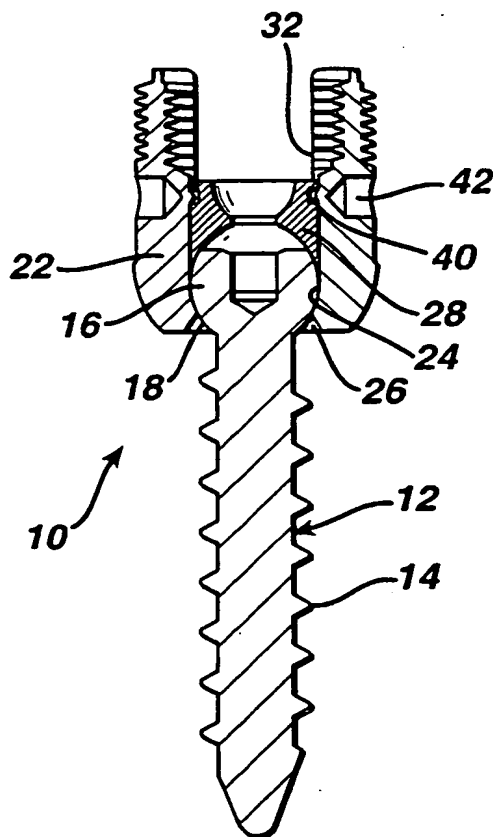
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

(72) Inventor: **GLASCOTT, Craig**; 6612 Pineview Court,
Boston Heights, OH 44236 (US).

[Continued on next page]

(54) Title: **POLYAXIAL SCREW WITH IMPROVED LOCKING**

(57) Abstract: A polyaxial pedicle screw assembly incorporates a concave portion on a receiver which mates with a convex surface on a head of the screw to form a ball joint. The radius of at least a portion of the concave surface is less than a radius of the mating convex portion whereby to create an interference fit.



WO 02/054966 A3

WO 02/054966 A3



(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

(88) Date of publication of the international search report:
26 September 2002

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/00814

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 748 387 A (STRYKER FRANCE SA) 14 November 1997 (1997-11-14) page 10, line 31 -page 11, line 3; figures 13,14 figure 7	1-6
A	US 5 681 319 A (HARMS JUERGEN ET AL) 28 October 1997 (1997-10-28) column 2, line 15 -column 3, line 8; figures 3-5	1-7
A	US 5 797 911 A (SHERMAN MICHAEL C ET AL) 25 August 1998 (1998-08-25) column 5, line 55 - line 62; figure 2	1-6,8
A	US 5 443 467 A (HARMS JUERGEN ET AL) 22 August 1995 (1995-08-22) column 3, line 5 - line 31; figures 1,2	1-7



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

19 June 2002

Date of mailing of the international search report

03/07/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Ducreau, F

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 02/00814

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2748387	A	14-11-1997	FR 2748387 A1	14-11-1997
			AU 733342 B2	10-05-2001
			AU 2082197 A	20-11-1997
			CA 2206152 A1	13-11-1997
			DE 807420 T1	20-05-1999
			EP 0807420 A1	19-11-1997
			ES 2121569 T1	01-12-1998
			JP 10043202 A	17-02-1998
			NZ 314798 A	27-05-1998
			US 6290703 B1	18-09-2001
			US 6022350 A	08-02-2000
US 5681319	A	28-10-1997	DE 19507141 A1	12-09-1996
US 5797911	A	25-08-1998	AU 734406 B2	14-06-2001
			AU 4491497 A	17-04-1998
			EP 0934027 A1	11-08-1999
			JP 2001501109 T	30-01-2001
			WO 9812976 A1	02-04-1998
			US 5885286 A	23-03-1999
US 5443467	A	22-08-1995	DE 4307576 C1	21-04-1994
			CA 2118562 A1	11-09-1994
			DE 59400258 D1	13-06-1996
			EP 0614649 A1	14-09-1994
			ES 2089867 T3	01-10-1996
			JP 2510476 B2	26-06-1996
			JP 6296621 A	25-10-1994
			KR 128371 B1	01-04-1998